4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0033]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0658. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water--21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h) (OMB Control Number 0910-0658)--Extension

The bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are Escherichia coli. The adulteration provision of the bottled water standard (§ 165.110(d)) provides that a finished product that tests positive for E. coli will be deemed adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require that source water from other than a public water system (PWS) be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are E. coli. Source water found to contain E. coli is not considered water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a

source that has tested positive for E. coli, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain E. coli will be considered negative for E. coli after five samples collected over a 24-hour period from the same sampling site are tested and found to be E. coli negative.

Description of Respondents: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

In the Federal Register of January 18, 2013 (78 FR 4152), FDA published a 60-day notice requesting public comment on the proposed extension of this collection of information. FDA received two letters in response to the notice, which contained multiple comments.

One comment suggested that laboratory quality assurance practices should be required for the testing of bottled water. FDA's CGMP regulations for bottled water in 21 CFR 129 do not specifically require laboratory quality assurance practices, and FDA does not have the specific statutory authority to require bottlers to use certified laboratories for water quality tests.[1] However, the CGMP regulations for source water testing do require that "[t]est and sample methods shall be those recognized and approved by the government agency or agencies having jurisdiction over the approval of the water source, and shall be consistent with the minimum [standard of quality] requirements set forth in § 165.110(b) of this chapter" (§ 129.35(a)(3)(ii)). The CGMP regulations also state that "[a]nalysis of the sample may be performed for the plant by competent commercial laboratories (e.g., Environmental Protection Agency (EPA) and State-certified laboratories)" (§ 129.35(a)(3)(iii)). For product water, the regulations also state that bottled water manufacturers will "[a]nalyze such samples by methods approved by the government agency or agencies having jurisdiction" (§ 129.80(g)(3)).

One comment noted that the EPA issued a final rule on February 13, 2013, that established a maximum contaminant level for E. coli and stated that E. coli is a more specific indicator of fecal contamination and the potential presence of associated pathogen occurrence than fecal coliforms. FDA agrees that E. coli is an appropriate indicator of fecal contamination and that the presence of fecal indicators demonstrates the potential for the presence of fecal pathogens. FDA requires bottled water manufacturers to sample and analyze source water obtained from other than a public water system for total coliform at least once each week. If any coliform organisms are detected, manufacturers must conduct followup testing to determine whether any of the coliform organisms are E. coli. Source water found to contain E. coli is not considered water of a safe, sanitary quality as required for use in bottled water. Manufacturers must also analyze product water samples at least once a week for total coliform, and, if any coliform organisms are detected, they must conduct followup testing to determine whether any of the coliform organisms are E. coli. Product water containing E. coli is considered adulterated. Thus, the presence of the fecal indicator E. coli is the key factor for determining whether source water is of a safe, sanitary quality, and whether product water is adulterated. FDA is reviewing the EPA final rule referenced in the comment (National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule, 78 FR 10269; February 13, 2013) to determine what actions, if any, FDA needs to take to respond to the rule.

To the extent that the comments recommended changes to FDA's bottled water regulations, which can only be accomplished by rulemaking, the comments were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

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[1] U.S. Government Accountability Office (GAO), 2009. Bottled Water: FDA Safety and Consumer Protections Are

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§§ 129.35(a)(3)(i) and 129.80(h)	319 (bottlers subject to source water and finished product testing)	6	1,914	0.08 (5 minutes)	153
§ 129.80(g) and 129.80(h)	95 (bottlers testing finished product only)	3	285	0.08 (5 minutes)	23
§§ 129.35(a)(3)(i) and 129.80(h)	3 (bottlers conducting secondary testing of source water)	5	15	0.08 (5 minutes)	1
§§ 129.35(a)(3)(i) and 129.80(h)	3 (bottlers rectifying contamination)	3	9	0.25 (15 minutes)	2
Total					179

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for E.coli are negligible. We estimate that the labor burden of keeping records of each test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for E. coli when total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about 3 times per year in source testing and about 3 times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs may find a total coliform positive sample about 3

Often Less Stringent Than Comparable EPA Protections for Tap Water.

times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for E. coli.

We expect that recordkeeping for the followup test for E. coli will also take about 5 minutes per test. As shown in table 1 of this document, we expect that 3 bottlers per year will have to carry out the additional E. coli testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, E. coli testing, and source rectification, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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